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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,018	01/07/2002	Seiichi P.T. Matsuda	HO-P02080US1	2605

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EXAMINER	
RAMIREZ, DELIA M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/041,018	MATSUDA ET AL.	
	Examiner	Art Unit	
	Delia M. Ramirez	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-79* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Claims 1-79 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, 25-32, drawn in part to a microorganism comprising exogenous nucleic acids encoding a geranylgeranylpyrophosphate synthase, a diterpene synthase, an HMG-CoA reductase, as well as a upc2-1 polynucleotide, classified in class 435, subclass 252.3.

II. Claims 19-24, drawn in part to a microorganism comprising exogenous nucleic acids encoding a geranylgeranylpyrophosphate synthase, an HMG-CoA reductase, as well as a upc2-1 polynucleotide, classified in class 435, subclass 252.3.

III. Claims 33-49, drawn to a method of producing a diterpene by culturing a microorganism comprising exogenous nucleic acids encoding a geranylgeranylpyrophosphate synthase, a diterpene synthase, an HMG-CoA reductase, as well as a upc2-1 polynucleotide, classified in class 435, subclass 41.

IV. Claims 50-58, drawn to a method of producing a diterpene by culturing a microorganism comprising exogenous nucleic acids encoding a geranylgeranylpyrophosphate synthase, an HMG-CoA reductase, as well as a upc2-1 polynucleotide, classified in class 435, subclass 41.

V. Claims 59-62, 66-68, drawn to a method of producing a diterpene by culturing a microorganism comprising a upc2-1 polynucleotide, exogenous nucleic acids encoding a geranylgeranylpyrophosphate synthase, a diterpene synthase, an HMG-CoA reductase,

and further comprising a modification in the nucleic acid encoding a squalene synthase, squalene epoxidase and/or lanosterol synthase, classified in class 435, subclass 41.

VI. Claims 63-65, drawn to a method of producing a diterpene by culturing a microorganism comprising a upc2-1 polynucleotide, exogenous nucleic acids encoding a geranylgeranylpyrophosphate synthase, an HMG-CoA reductase, and further comprising a modification in the nucleic acid encoding a squalene synthase, squalene epoxidase and/or lanosterol synthase, classified in class 435, subclass 41.

VII. Claims 69-71, drawn to a method of producing diterpene by culturing a microorganism comprising a upc2-1 polynucleotide, exogenous nucleic acids encoding a geranylgeranylpyrophosphate synthase, a diterpene synthase, an HMG-CoA reductase, and further comprising a modification in the nucleic acid encoding a prenyltransferase, classified in class 435, subclass 41.

VIII. Claims 72-74, drawn to a method of producing diterpene by culturing a microorganism comprising a upc2-1 polynucleotide, exogenous nucleic acids encoding a geranylgeranylpyrophosphate synthase, an HMG-CoA reductase, and further comprising a modification in the nucleic acid encoding a prenyltransferase, classified in class 435, subclass 41.

IX. Claims 75-76, drawn to a method of producing a diterpene by culturing a microorganism comprising a upc2-1 polynucleotide, exogenous nucleic acids encoding a geranylgeranylpyrophosphate synthase, a diterpene synthase, an HMG-CoA reductase, and further comprising a modification in the nucleic acid encoding a hexaprenylpyrophosphate synthetase, classified in class 435, subclass 41.

X. Claims 77-78, drawn to a method of producing a diterpene by culturing a microorganism comprising a upc2-1 polynucleotide, exogenous nucleic acids encoding a

geranylgeranylpyrophosphate synthase, an HMG-CoA reductase, and further comprising a modification in the nucleic acid encoding a hexaprenylpyrophosphate synthetase, classified in class 435, subclass 41.

XI. Claim 79, drawn to a method of isolating a diterpene synthase by using microorganisms comprising exogenous nucleic acids encoding a geranylgeranylpyrophosphate synthase, an HMG-CoA reductase, as well as a upc2-1 polynucleotide, classified in class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the microorganism of Group I comprises a nucleic acid encoding a diterpene synthase not required in the microorganism of Group II. Furthermore, the microorganisms of Group I and II have not been disclosed as capable of use together, have different effects, and express different proteins.

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the microorganism of Invention I can be used in the method of Invention III as well as to produce the proteins encoded by the exogenous nucleic acids.

4. Inventions II, IV and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the

microorganism of Invention II can be used in the distinct methods of Inventions IV and XI as well as to produce the proteins encoded by the exogenous nucleic acids.

5. Inventions I, II and V-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case none of the microorganisms of Inventions I and II is either used or made by the methods of Inventions V-X. The microorganisms required by the methods of Inventions V-X require additional modifications not present in the microorganisms of Inventions I or II.

6. Inventions III-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Inventions III-XI may comprise different steps, may use different products and/or produce different results.

7. In addition to the election of one invention as indicated above, Applicants are required to elect a single combination of exogenous nucleic acids from the list of sequence identifiers recited in the claims. For example, if Applicants elect the microorganism of Group I, applicants are requested to elect one nucleic acid encoding the geranylgeranylpyrophosphate synthase from SEQ ID NO: 1-85, and one nucleic acid encoding the diterpene synthase from the sequences recited in claims 3, 27, 31. Since no specific sequence identifiers have been recited in regard to the nucleic acid encoding the HMG-CoA reductase or the upc2-1 polynucleotide, no election is required at this time. However, if the claims are amended to recite several specific sequence identifiers for nucleic acids encoding HMG-CoA and upc2-1, Applicants will be requested to elect a single nucleic acid encoding an HMG-CoA and a single upc2-1 polynucleotide.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, as shown by their different classification, restriction for examination purposes as indicated is proper.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

10. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting

rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143).

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 872-9306. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or

relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
June 22, 2004

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
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